CROSS FILE SHEET

FILE NO: 96P-0500 /C 33

SEE FILE NO: 91N-384H /OB 16

Salt Institute

April 8, 1999 ™

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

RE: Food Labeling; Nutrient Content Claims, Definition of Term: Healthy; Extension of Partial Stay; Docket Nos. 96P-0500 and 91N-384H

The Salt Institute is pleased that FDA, on March 16th, extended for three years the imposition of second-tier definitions for sodium to define the term "healthy" as used on FDA-regulated nutrition labels.[1] We agree with the FDA's assessment that there are "strong and opposing views" on this issue – as on the overall issue of the wisdom and value of universal sodium restriction as the underlying public health nutrition policy, and the accuracy and appropriateness of sodium health claims.

As the extension notice points out, the label notice of "healthy" is designed to give consumers useful information on how to fashion a better diet, which FDA describes as "consistent with dietary guidelines." Inasmuch as the Dietary Guidelines for Americans are under revision currently, the extension will allow FDA to consider the updated Guidelines. Likewise, there have been many recent studies and sharp professional debate among expert researchers about whether reduced sodium diets confer health benefits to the general population. Last year, *Science* magazine investigated the issue and recommended an independent review of the issue.[2] The National Heart, Lung and Blood Institute sponsored a Workshop on Sodium and Blood Pressure in January, 1999, where the experts voiced widely disparate views about the wisdom and usefulness of the current strategy. This month, the program of the FASEB annual meeting features a debate on this very issue. The following month, at the annual meeting of the American Society of Hypertension major sessions deal with the issue. Later this year, the American Council on Nutrition is sponsoring a special symposium on sodium and blood pressure and public policy. Clearly, this issue remains unsettled and is a priority for these groups. It is entirely appropriate that FDA defer action on this issue while this vigorous debate among hypertension researchers continues so that FDA policy can reflect "significant scientific agreement" among the experts.

We also totally agree with FDA that the term "healthy" should be reserved for circumstances where real health benefits can be expected. For most Americans, that would exclude any consideration of dietary sodium for two reasons.

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First, it is not the concentration of sodium that is in question, but total sodium; it is not a "good foods/bad foods" question, but rather a "good diet/bad diet" question. Data from a new USDA study (which we have not yet seen in print) presented at the March meeting of the HHS/USDA Dietary Guidelines Advisory Committee[3] indicated that the sodium concentration of the U.S. diet declining. But sodium intakes remain unchanged in the century since we've been able to measure urinary sodium. People may be trying to "comply" with the Dietary Guidelines by consuming food portions lower in sodium, but, like other animal species, they continue to eat salt, if it is available, until they consume their normal intakes (120-180 mmol Na is the range identified in the Intersalt Study and other well-controlled investigations and seemed to be well-accepted at the January NHLBI Workshop on Sodium and Blood Pressure). Thus, even if one were to assume that a lower sodium diet would confer a health benefit, consumption of low-sodium food items does not translate into a lower sodium diet overall.

Second, evidence suggests that low-sodium diets may not be providing the projected health benefit. Only a minority of the population will benefit from reducing dietary sodium. Overall, because individuals vary in blood pressure sensitivity to salt, there is no significant blood pressure reduction. This is the experience in clinical trials where highly-motivated and professionally-supervised hypertensive subjects consume reduced sodium diets; especially for older hypertensive patients, there can be benefits, but not for the general population.[4] Experience also teaches the difficulty of sustaining low-sodium diets over time, and the evidence suggests that even for those who sustain the intervention, the blood pressure benefits dissipate over time.[5] Perhaps even more significant is the fact that of the six studies focused on health outcomes[6] (e.g. incidence of heart attacks or morbidity/mortality outcomes), none have found low-sodium diets superior to current intake levels, and at least two have suggested a potential for adverse outcomes, namely increased incidence of heart attacks.[7] Thus, the underpinnings for the current public health nutrition policy of universal sodium restriction have been called into serious question.

For these reasons, FDA should take advantage of this three-year extension to reexamine the basic question of whether any consideration should be taken of the sodium levels of foods in awarding the privilege of designating a food to be "healthy."

Recognizing the current scientific turmoil on these issues, we would suggest and recommend that FDA summarize its understanding of the issues 180-270 days before its new January 1, 2003 deadline and solicit further public comments at that time.

Sincerely,

Richard L. Hanneman

Richard L. Hanneman
President

cc: Joseph Levitt
TA6479

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[1] 64 *Federal Register* 50: 12886-87 (March 16,1999)

[2] Gary Taubes, "The (Political) Science of Salt." 281 *Science* 898-907 (14 August 1998). See especially pages 903-905.

[3] The transcript can be found online at <http://www.ars.usda.gov/dgac/>.

[4] Julian P. Midgley et al., "Effect of Reduced Dietary Sodium on Blood Pressure," 275 *JAMA* 1590 (1996). and Niels A. Graudal et. al., "Effects of Sodium Restriction on Blood Pressure, Renin, Aldosterone, Catecholamines, Cholesterols, and Triglyceride," 279 *JAMA* 1383 (1998).

[5] The Trials of Hypertension Prevention Collaborative Research Group, "Effects of Weight Loss and Sodium Reduction Intervention on Blood Pressure and Hypertension Incidence in Overweight People With High-Normal Blood Pressure." 157 *Archives of Internal Medicine* 657 (1997).

[6] Michael H. Alderman, et. al. "Low Urinary Sodium Is Associated With Greater Risk of Myocardial Infarction Among Treated Hypertensive Men." 25 *Hypertension* 1144-1152 (1995). Jeffrey A. Cutler, presented May 30, 1997 at American Society of Hypertension. Hugh Tunstall-Pedoe, et. al. "Comparison of the Prediction by 27 Different Factors of Coronary Heath Disease and Death in Men and Women of the Scottish Heart Health Study: Cohort Study." 315 *British Medical Journal* 722-729 (1997). Michael H. Alderman, et. al. "Dietary Sodium Intake and Mortality: the National Health and Nutrition Examination Survey (NHANES I)." 351 *The Lancet* 781-785 (1998). Veli-Pekka Valkonen. "Sodium and Potassium Excretion and the Risk of Acute Myocardial Infarction." Presented to American Heart Association Scientific Sessions, Dallas, TX, October 15, 1998. Jerome D. Cohen, presented January 28, 1999 at NHLBI Workshop on Sodium & Blood Pressure.

[7] Ibid. Both Alderman studies.

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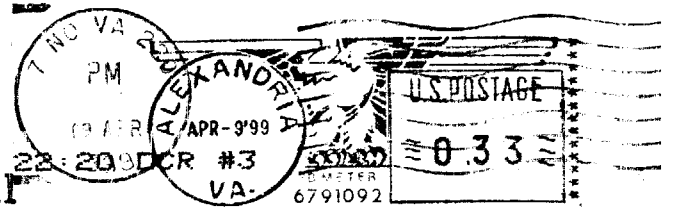

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